



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2018-N-4839]**

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Registering with the Center for Veterinary Medicine's Electronic Submission System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0454. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Registering with the Center for Veterinary Medicine's Electronic

Submission System--21 CFR 11.2

OMB Control Number 0910-0454--Extension

FDA's "Electronic Records; Electronic Signatures" regulation (21 CFR part 11) requires that we identify in the Electronic Submission Docket (Docket No. FDA-1992-S-0039) the types of documents or parts of documents acceptable for official electronic submission. FDA's Center for Veterinary Medicine (CVM) has placed notifications in that docket identifying documents acceptable for electronic submission to the Center, as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of FDA's "Electronic Records; Electronic Signatures" regulation.

The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office. The CVM's Electronic Submission System (ESS) is a Center-wide solution for accepting electronic regulatory submissions. The CVM ESS is used to accept electronic submissions for animal and veterinary products.

Our Guidance for Industry (GFI) #108 entitled "Registering with the Center for Veterinary Medicine's Electronic Submission System" outlines general standards to be used for

the submission of any electronic information to CVM using the FDA ESG, including how to register with the CVM ESS using Form FDA 3538, “Electronic Submission System Participant Management.” Registering with the CVM ESS allows respondents to send electronic regulatory submissions to the Office of New Animal Drug Evaluation, the Office of Surveillance and Compliance’s Division of Animal Feeds and Division of Surveillance, and the Office of Minor Use and Minor Species Animal Drug Development.

Respondents use GFI #108 and Form FDA 3538 to facilitate the electronic submission of regulatory information. We use the information collected with Form FDA 3538 to register respondents to use the CVM ESS.

*Description of Respondents:* The respondents are submitters of regulatory information to CVM.

In the *Federal Register* of April 16, 2019 (84 FR 15621), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
11.2	Form FDA 3538	193	1.3	251	0.08 (5 minutes)	20

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In the 60-day notice published April 16, 2019, we based our estimate of 179 respondents per year on our experience with the submission of electronic information using the CVM ESS and the number of electronic registration or change requests received between January 1, 2018, and November 30, 2018. We are now adjusting our estimate to 193 respondents per year to

better reflect the data for the time period January 1 to December 31, 2018. Using these new figures, our estimated burden for the information collection reflects an overall increase from the previous OMB approval of 17 hours and a corresponding increase of 213 responses. We attribute this adjustment to the reauthorizations of both the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act, which require sponsors to submit information electronically to the CVM's Office of New Animal Drug Evaluation. Because of this requirement, sponsors are now registering to use the CVM ESS in greater numbers than in previous years.

**Dated:** October 4, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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